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Troy J. Cole
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204-5137

EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
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1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,958	BURKE ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/20/07 (amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *41-59* is/are allowed.

6)☒ Claim(s) *1-40 and 60-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of December 20, 2007 ("Amendment") does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed December 20, 2007 have been fully considered but they are not persuasive.

The rejections of claims 1, 5, and 9 under 35 USC 103(a) as being obvious over Neel in view of Microsystem Design

Microsystem Design only pertains to …

Applicant argues, on pages 20-21 of the Amendment, "Microsystem Design only pertains to vertical capillaries," "… only pertains to static fluid fronts," and "… only

pertains to vertical capillaries immersed in external pools of liquid." The Examiner respectfully disagrees.

As for Microsystem Design only pertaining to vertical capillaries, Microsystem Design states on page 321,

> The fluid in the meniscus forms an acute angle θ within the wall of the capillary, called the *contact angle*. The contact angle is a characteristic of the various interfaces involved, and can vary from convex for liquids that wet the surface to concave for nonwetting liquids.
>
> Contact angles depend both on the wetting liquid and the chemistry and can be sensitive to contamination and the effects of roughness.

There is no suggestion in Microsystem Design that gravity controls the shape of the flow front. Gravity is mentioned only in regard to balancing surface tension with atmospheric pressure. So gravity affects the height of the fluid front. While gravity may also affect the shape of the fluid front, which is not mentioned or suggested by Microsystem Design, this effect would only be secondary to the nature of the wetting liquid and the chemistry of the capillary inner wall surface. Indeed, US Patent No. 6,557,427 B2, which is entitled "Capillaries for fluid movement within microfluidic channels," states in column 1,

> Capillary action is well known in the prior art for moving liquids through microchannels. This movement is defined as the movement of a liquid within the spaces of a porous material due to the forces of adhesion, cohesion, and surface tension . . .

> Often, capillaries provide the sole driving source for the movement of liquid through the device. Accordingly, *careful fabrication of the capillary to exact dimensions is required, and the composition of the walls is selected so as to provide the desired degree of wetting and surface tension*, as the device is used without ancillary motive force." [emphasis added].

Ichikawa et al. in a paper on the interface dynamics of capillary flow in a tube under negligible gravity condition[1], such as in a horizontal tube, found, "The dynamic contact angle is determined by the balance of the three interface forces [gas-liquid, liquid-solid, and solid-gas interfaces] and other forces from the liquid such as inertia force and viscous force."[2]

As for Microsystem Design only pertaining to static fluid fronts, it should be noted that the Figure 13.3 caption states, "Illustrating the *rise* of a wetting liquid in a capillary due to surface tension forces." While the contact angle of the fluid flow front would be expected to vary as the fluid flows, its basic shape, that is convex or concave, would not be expected to change unless the flow conditions substantially changed.

As for Microsystem Design only pertaining to vertical capillaries immersed in external pools of liquid, see the comments above about Microsystem Design only pertaining to vertical capillaries. Also consider the Ichikawa et al. paper referred to above.

Applicants should also consider Yang et al's article on the marching velocity of capillary meniscuses in microchannels[3] and Kim et al. article on micro-channel filling

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[1] Ichikawa et al., Interface Dynamics of Capillary Flow in a Tube under Negligible Gravity Condition, Journal of Colloid and Interface Science 162, 350-355 (1994).
[2] ibid at page 354, second, column.
[3] Yang et al., Marching Velocity of Capillary Meniscuses in Microchanels, IEEE 2002.

flow considering surface tension effect[4] in both of which gravity is not a term in mathematical equations regarding the flow front of a fluid in a microchannel. Weigl et al. US 6,557,427 B2 (referred to already above) has an equation that models blood flow in a microlfuidic conduit, albeit a rectangular channel, in which gravity is not a term. See col. 03: 55 – col. 04:02. In fact, Weigl can predict how far and fast a blood sample can advance into the microchannel based in part on the contact angle of the sample. See col. 04:03-20.

Claims 1 and 5 are method claims

Applicant argues on page 21 of the Amendment, '… the Office action ignores the fact that claims 1 and 5 are method claims. Claims 1 and 5 specifically require the step of "determining the presence or absence of a response to the test signal above a predetermined threshold, the response indicating that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat.' See page 21 of the amendment. The Examiner respectfully disagrees. While Neel as modified by Microsystem Design does not explicitly state this limitation, as pointed out in the rejections (see bottom of page 4 through page 5 of the Office action of September 25, 2007) at least three of the embodiments of Neel's biosensor inherently meet this limitation:

[4] Kim et al., Micro-channel filling flow considering surface tension effect, J. Micromech. Microeng. 12

> Neel, in fact, discloses three ways of adapting the embodiment of Figure 2 that would create a response as claimed, although not stated to do so: (a) placing the second fill detection electrode behind the first fill detection electrode, which would practically ensure that the measurement zone has been substantially occupied before response above a predetermined threshold is given (col. 08:18-33); (b) narrowing the capillary region over the fill electrodes (col. 08:18-33); or (c) changing the threshold (determined by calibration) for determining whether a response indicates that the measurement zone has been substantially occupied (col. 14:11-26).

Applicants have not commented on why these embodiments of Neel would not preclude or lessen the negative effect of non-uniform flow front on dose sufficiency.

Applicants state on page 21 of the Amendment, "Only the present Applicants have performed the test, as detailed in the present specification, to recognize that this problem [that a non-uniform flow front in a biosensor capillary channel can be of a magnitude significant enough to give a false indication of dose sufficiency] exists. The Examiner respectfully disagrees. Applicants are directed to Tokunaga et al. US 2003/0175946 A1 paragraphs [0008], [0009], [0015]; claim 1; and Figures 5 and 6, which show that the problem addressed by Applicants was recognized by at least one other group at the time of the invention.

(2002) 236-246.

Claims 2-4 and 6-8 were rejected under 35 U.S.C. 103(a) as being obvious over Neel in view of Microsystem Design, Beaty, and Bedell

Applicants argue on pages 22-23 of the Amendment, "Therefore, a combination of Neel and Beaty teaches that the separate dose sufficiency electrodes of Neel are unnecessary since the application of an AC signal to the measurement electrodes achieves the same result without the need for an additional pair of dose sufficiency electrodes." The Examiner respectfully disagrees. Neel teaches (column 8) additional benefits to having separate dose sufficiency electrodes that would accrue even if only AC signals as taught by Beaty were used for determining dose sufficiency:

> However they are arranged relative to each other, it is preferable for fill-detect electrodes **28** and **30** to be located on the distal side of reagent layer **90**. In this way, as the sample flows through sample chamber **88** toward distal end **70**, the sample will have traversed reagent layer **90** by the time it reaches fill-detect electrodes **28** and **30**. This arrangement beneficially allows the fill-detect electrodes **28** and **30** to detect not only whether sufficient blood sample is present in sample chamber **88** but also to detect whether the blood sample has become sufficiently mixed with the chemical constituents of reagent layer **90**. Thus, if reagent layer **90** covers working electrode **22**, as is preferable, then it is preferable to locate fill-detect electrodes **28** and **30** on the distal side of working electrode **22**, as in the configuration shown in FIGS. **1–3**. Other configurations may be used, however.

Additionally Beaty teaches that the AC signal may have a DC offset to aid in determining the concentration of the interferant of interest. See the bottom of page 16 - page 17. In this case it would be useful to provide separate dose sufficiency electrodes for a similar reason acknowledged by Applicant, not to disturb the reaction between the sample and the reagent in the measurement zone with the DC offset.

Claims 10, 11, 14-17, 20-22, 25-29, 32, 33, and 36-38 were rejected under 35 U.S.C. 103(a) as being obvious over Neel in view of Beaty. Claims 12, 13, 18, 19, 23, 24, 30, 31, 34, 35, 39, and 40 were rejected under 35 U.S.C. 103(a) as being obvious over Neel in view of Beaty, and Bedell.

Applicants argue on pages 24-25 of the Amendment, "Therefore, a combination of Neel and Beaty teaches that the separate dose sufficiency electrodes of Neel are unnecessary since the application of an AC signal to the measurement electrodes achieves the same result without the need for an additional pair of dose sufficiency electrodes." The Examiner respectfully disagrees. Neel teaches (column 8) additional benefits to having separate dose sufficiency electrodes that would accrue even if only AC signals as taught by Beaty were used for determining dose sufficiency:

However they are arranged relative to each other, it is preferable for fill-detect electrodes **28** and **30** to be located on the distal side of reagent layer **90**. In this way, as the sample flows through sample chamber **88** toward distal end **70**, the sample will have traversed reagent layer **90** by the time it reaches fill-detect electrodes **28** and **30**. This arrangement beneficially allows the fill-detect electrodes **28** and **30** to detect not only whether sufficient blood sample is present in sample chamber **88** but also to detect whether the blood sample has become sufficiently mixed with the chemical constituents of reagent layer **90**. Thus, if reagent layer **90** covers working electrode **22**, as is preferable, then it is preferable to locate fill-detect electrodes **28** and **30** on the distal side of working electrode **22**, as in the configuration shown in FIGS. **1–3**. Other configurations may be used, however.

Additionally Beaty teaches that the AC signal may have a DC offset to aid in determining the concentration of the interferant of interest. See the bottom of page 16 - page 17. In this case it would be useful to provide separate dose sufficiency electrodes for a similar reason acknowledged by Applicant, not to disturb the reaction between the sample and the reagent in the measurement zone with the DC offset.

Claims 60-65 were rejected under 35 U.S.C. 103(a) as being obvious over Neel

Applicants argue on pages 25-29 for an unexpected benefit to having the relative first and second lengths of the dose sufficiency electrodes or the relative first and second axes of the dose sufficiency electrodes be as claimed. However, this benefit accures for the test strip "when used with AC excitation." None of claims 60-65 require means for applying AC excitation to the dose sufficiency electrodes. This not even an intended use. Thus, although the Examiner acknowledges Applicants' discovery of this unexpected benefit for the claimed relative lengths of the electrodes, it is a moot point, unless means or a method step for providing AC excitation becomes a limitation of these claims.

Status of the Rejections pending since the Office action of September 25, 2007

3. The rejection of claims 1, 5, and 9 under 35 U.S.C. 103(a) as being obvious over Neel as modified by Microsystem Design are withdrawn, but are recast below in light of Applicants' Amendment.

4. The rejection of claims 1, 5, and 9 under 35 U.S.C. 103(a) as being obvious over Neel as modified by Microsystem Design are restated below for Applicants' convenience.

5. The rejection of claims 10, 11, 14-17, 20-22, 25-29, 32, 33, and 36-38 under 35 U.S.C. 103(a) as being obvious over Neel as modified by Beaty are either withdrawn, but are recast below in light of Applicants' Amendment, or restated below for Applicants' convenience.

6. The rejection of claims 12, 13, 18, 19, 23, 24, 30, 31, 34, 35, 39, and 40 under 35 U.S.C. 103(a) as being obvious over Neel as modified by Beaty and Bedell are restated below for Applicants' convenience.

7. The rejection of claims 51, 52, 57, and 58 under 35 U.S.C. 112, second paragraph, are withdrawn.

8. The rejection of claims 60-65 under 35 U.S.C. 103(a) as being obvious over Neel are restated below for Applicants' convenience.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) ("Neel") in view of pages 320-322 of Microsystem Design by Stephen Senturia, Kluwer Academic Publishers (2002) ("Microsystem Design").

Addressing claim 1, Neel discloses a method of determining dose sufficiency in a test strip for performing a measurement on a biological fluid comprising: providing a biological fluid test strip (Figures 1-3), comprising: a capillary fill chamber (88) extending a length along the test strip from an intake opening (68) to a terminus (70), at least two measurement electrodes (22, 24 – note that according to Applicants' specification a working electrode and a counter/reference electrode are measurement electrodes, top of page 53) disposed in the capillary fill chamber between the opening and the terminus (Figures 2 and 3), the measurement electrodes defining a measurement zone (Figures 2 and 3), and at least two dose sufficiency electrodes (60,

62) defining a gap therebetween (Figure 2) and in operative communication with the capillary fill chamber (Figure 2), the electrodes located between the measurement zone and the terminus (Figure 2); applying the biological fluid to the opening (344- Figure 17), whereby the fluid flows from the opening toward the terminus (col. 14:43-51 and col. 14:63-65); applying a test signal to a least one of the does sufficiency electrodes (col. 14:66 – col. 15:03); determining the presence or absence of a response to the test signal above a predetermined threshold, the response indicating that the fluid has occupied substantially all of the measurement zone (col. 15:03-11).

Neel does not mention whether the flow includes a flow front selected from one of a concave, a convex and a substantially flat flow front and thus whether the response indicates that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to have the fill detection region adapted (if not already so adapted) so that the response of the second fill electrode indicates that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat because Neel desires for the sample to reach the fill electrodes not only until after the sample has traversed the reagent layer, but also after the sample has been sufficiently mixed with the chemical constituents of the reagent layer (see col. 08:18-33). With this desire in mind, since it was known at the time of the invention that the profiles of the fluid flow fronts in microchannels can have different shapes, such as concave or convex, depending on the fluid, chemistry of the

capillary surface, contamination, and surface roughness (see Microsystem Design) one with ordinary skill in the art would adapt the fill detection region so as not to be influenced in its fill sufficiency determination by the shape of the fluid flow front. Neel, in fact, discloses three ways of adapting the embodiment of Figure 2 that would create a response as claimed, although not stated to do so: (a) placing the second fill detection electrode behind the first fill detection electrode, which would practically ensure that the measurement zone has been substantially occupied before response above a predetermined threshold is given (col. 08:18-33); (b) narrowing the capillary region over the fill electrodes (col. 08:18-33); or (c) changing the threshold (determined by calibration) for determining whether a response indicates that the measurement zone has been substantially occupied (col. 14:11-26).

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claim 5, Neel discloses a method of determining dose sufficiency in a test strip for performing a measurement on a biological fluid comprising: providing a biological fluid test strip (Figures 1-3), comprising: a fluid flow intake opening (68), a fluid flow terminus (70), at least two measurement electrodes (22, 24 – note that according to Applicants' specification a working electrode and a counter/reference electrode are measurement electrodes, top of page 53) disposed on the test strip between the opening and the terminus (Figure 3), the measurement electrodes defining a measurement zone (Figures 2 and 3), and at least two dose sufficiency electrodes (60, 62) defining a gap therebetween (Figure 2) and located between the measurement zone and the terminus (Figure 2); applying the biological fluid to the opening (344- Figure 17), whereby the fluid flows from the opening toward the terminus (col. 14:43-51 and col. 14:63-65); applying a test signal to at least one of the does sufficiency electrodes (col. 14:66 – col. 15:03); determining the presence or absence of a response to the test signal above a predetermined threshold, the response indicating that the fluid has occupied substantially all of the measurement zone (col. 15:03-11).

Neel does not mention whether the flow includes a flow front selected from one of a concave, a convex and a substantially flat flow front and thus whether the response indicates that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat.

However, it would have been obvious to one with ordinary skill in the art at the time of the invention to have the fill detection region adapted (if not already so adapted) so that the response of the second fill electrode indicates that the fluid has occupied substantially all of the measurement zone regardless of whether the flow front is concave, convex or substantially flat because Neel desires for the sample to reach the fill electrodes not only until after the sample has traversed the reagent layer, but also after the sample has been sufficiently mixed with the chemical constituents of the reagent layer (see col. 08:18-33). With this desire in mind, since it was known at the time of the invention that the profiles of the fluid flow fronts in microchannels can have different shapes, such as concave or convex, depending on the fluid, chemistry of the capillary surface, contamination, and surface roughness (see Microsystem Design) one with ordinary skill in the art would adapt the fill detection region so as not to be influenced by the shape of the fluid flow front. Neel, in fact, discloses three ways of adapting the embodiment of Figure 2 that would create a response as claimed, although not stated to do so: (a) placing the second fill detection electrode behind the first fill detection electrode, which would practically ensure that the measurement zone has been substantially occupied before response above a predetermined threshold is given (col. 08:18-33); (b) narrowing the capillary region over the fill electrodes (col. 08:18-33); or (c) changing the threshold (determined by calibration) for determining whether a response indicates that the measurement zone has been substantially occupied (col. 14:11-26).

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claim 9, for the additional limitations of this claim see Figures 1-3 in Neel and note capillary fill chamber (88) and reagent (90).

11. Claims 2-4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) ("Neel") in view of pages 320-322 of Microsystem Design by Stephen Senturia, Kluwer Academic Publishers (2002) ("Microsystem Design") as applied to claims 1, 5, and 9 above, and further in view of Beaty et al. (WO

99/32881 A1) ("Beaty") and Bedell ("Admittance and Impedance Loci," Proc. Phys. Soc. London **14** 327-336) ("Bedell").

Neel as modified by Microsystem Design uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel as modified by Microsystem Design because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

For claims 3, 4, 7, and 8 note that Beaty states, "The real and imaginary components of the AC *impedance* of the biosensor …through a suitable frequency range … throughout some portion of which the parameter to be determined, be it sample identity, sample *volume*, … *varies with sufficient magnitude and phase* and is optimally uncoupled from, that is independent from, the concentration of other components of the sample on the cell 31. [emphasis added]" See page 16:20-30. For claim 4 further note that admittance is the reciprocal of impedance. See the Bedell article, especially the second full paragraph on page 328 and the last full paragraph on

page 332. Thus, barring a contrary showing, having the response comprise an admittance value is an obvious variant of a response that has an impedance value.

12. Claims 10, 11, 14-17, 20-22, 25-29, 32, 33, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) ("Neel") in view of Beaty et al. (WO 99/32881 A1) ("Beaty").

Addressing claims 10 and 11, Neel discloses a method of determining dose sufficiency in a test strip for performing a measurement on a biological fluid comprising: providing a biological fluid test strip (Figures 1-3), comprising: a capillary fill chamber (88) extending a length along the test strip,

at least two measurement electrodes (22,24) inoperative communication with the chamber (Figures 2 and 3), and

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber (Figure 2);

applying a biological fluid to the test strip (344 – Figure 17 and col. 04:25-34);

applying a dose sufficiency test signal to one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and

measuring a response to the dose sufficiency test signal at the other of the dose sufficiency electrodes (col. 15:03-11).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claims 14, and 25, for the additional limitations of these claims note that Applicant himself discloses an edge effect occurs when an AC test signal is applied to dose sufficiency electrodes placed nearly side-by-side, except for a small gap. See the bottom paragraph on page 56 of the specification. That, is based on Applicant's disclosure, an edge effect as shown in Applicant's Figure 36 would be an expected *property* when an AC test signal, as taught by Beaty, is applied to the similarly situated dose sufficiency electrodes in Figures 2 and 3 of Neel.

Addressing claims 15 and 26, for the additional limitations of these claims see in Beaty page 16:20-24.

Addressing claims 16 and 17, Neel discloses a method of determining a fill sufficiency in a test strip for performing a measurement on a biological fluid comprising: providing a biological fluid test strip (Figures 1-3), including: a capillary fill chamber (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

a measurement zone in the chamber positioned intermediate the opening and the terminus (volume of the chamber above the measurement electrodes (22,24),

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber and located between the measurement zone and the terminus (Figure 2);

introducing the biological fluid to the opening effective to cause the fluid to flow toward the terminus whereby the chamber is filled (344 – Figure 17 and col. 04:25-34);

applying a test signal to at least one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and

detecting a response or an absence of the response to the test signal effective to indicate the fill sufficiency of the biological fluid (col. 15:03-11).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See

page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

Addressing claims 20 and 22, Neel discloses a method of determining a dose sufficiency in a test strip for performing a measurement on a biological fluid (Figures 1-3), comprising:

providing a biological fluid test strip comprising:

a fluid flow intake opening (68);

a fluid flow terminus (70);

at least two measurement electrodes (22, 24 – note that according to Applicants' specification a working electrode and a counter/reference electrode are measurement electrodes, top of page 53) disposed on the test strip between the opening and

the terminus (Figure 3), the measurement electrodes defining a measurement zone (Figures 2 and

3);

and at least two dose sufficiency electrodes (60, 62) defining a gap therebetween and located between the measurement zone and the terminus (Figure 2);

applying the biological fluid to the test strip (col. 14:66 – col. 15:03);

applying a dose sufficiency test signal to at least one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and measuring a response to the dose sufficiency test signal (col. 15:03-11).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be

(col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claims 21 and 28, for the additional limitations of this claim see Figures 1-3 and note the capillary fill chamber (88) and the reagent (90).

Addressing claims 27 and 29, Neel discloses a method of determining a fill sufficiency in a test strip for performing a measurement on a biological fluid (Figures 1-3), comprising:

providing a biological fluid test strip comprising:

a fluid flow intake opening (68);

a fluid flow terminus (70);

a measurement zone in the chamber positioned intermediate the opening and the terminus (volume of the chamber above the measurement electrodes (22,24),

and at least two dose sufficiency electrodes (60, 62) positioned intermediate the measurement zone and the terminus (Figure 2);

introducing the biological fluid to the opening effective to cause the fluid to flow toward the terminus (344 – Figure 17 and col. 04:25-34);

applying a test signal to at least one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and

detecting a response or an absence of the response to the test signal effective to indicate the volume sufficiency of the biological fluid (col. 15:03-11).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claims 32 and 33, Neel discloses a method of determining dosage fill level in a test strip for performing a measurement on a biological fluid comprising:

providing a biological fluid test strip (Figures 1-3), including:

a capillary fill chamber (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

at least two measurement electrodes (22,24) inoperative communication with the chamber (Figures 2 and 3), and

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber (Figure 2) the dose sufficiency electrodes (60, 62) positioned to define a gap between one another (Figure 2);

dosing the test strip with a biological fluid effective to cause the biological fluid to begin to fill the chamber (344 – Figure 17 and col. 04:25-34);

applying a test signal to at least one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and

measuring a response to the signal at the other of the dose sufficiency electrodes (col. 15:03-11);

determining whether there is a sufficient dosage level (col. 15:03-11 and col. 14:11-26).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

Addressing claim 36, for the additional limitation of this claim note that Applicant discloses that when an AC test signal is applied to dose sufficiency electrodes placed nearly side-by-side, except for a small gap, "… there is substantially no electrical communication between the electrodes until the sample covers at least a portion of the edges along the electrode gap." See the bottom of page 56 of the specification to the last paragraph on page 57. That is, that the response varies in correlation with the degree to which the biological fluid bridges the gap would be an expected *property* when an AC test signal, as taught by Beaty, is applied to the similarly situated dose sufficiency electrodes in Figures 2 and 3 of Neel.

Addressing claims 37 and 38, Neel discloses a method of determining a fill level in a test strip for performing a measurement on a biological fluid comprising:

providing a test strip (Figures 1-3) including:

a capillary fill chamber (88) extending a length along the test strip from an opening (68) to a terminus (70),

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber (Figure 2) the dose sufficiency electrodes (60, 62) positioned to define a gap between one another (Figure 2);

introducing the biological fluid to the opening effective to cause the fluid to flow toward the terminus whereby the chamber is filled (344 – Figure 17 and col. 04:25-34);

applying a test signal to one of the dose sufficiency electrodes (col. 14:66 – col. 15:03); and

measuring a response to the signal at the other of the dose sufficiency electrodes (col. 15:03-11);

determining whether there is a sufficient dosage level (col. 15:03-11 and col. 14:11-26).

Neel uses a DC test signal (implied by col. 14:11-26).

Beaty (US 6,645,368 B1) discloses applying an AC test signal to test electrodes to determine sample volume sufficiency in an electrochemical test strip. See the abstract; Figure 2; and col. 06:20-42.

It would have been obvious to one with ordinary skill in the art at the time of the invention to use an AC test signal as taught by Beaty in the invention of Neel because

as taught by Beaty both sample identity and sample volume can then be determined with little affect from hematocrit and glucose (or other analyte) concentration. See page 08:23 – page 09:07 and page 12 :31 – page 13 :06.

13. Claims 12, 13, 18, 19, 23, 24, 30, 31, 34, 35, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) ("Neel") in view of Beaty et al. (WO 99/32881 A1) ("Beaty") as applied to claims 10, 11, 14-17, 20-22, 25-29, 32, 33, 36-38 above, and further in view of Bedell ("Admittance and Impedance Loci," Proc. Phys. Soc. London **14** 327-336) ("Bedell").

Addressing claims 12, 13, 18, 19, 23, 24, 30, 31, 34, 35, 39, and 40 for the additional limitations of these claims note that Beaty states, "The real and imaginary components of the AC *impedance* of the biosensor …through a suitable frequency range … throughout some portion of which the parameter to be determined, be it sample identity, sample *volume*, … *varies with sufficient magnitude and phase* and is optimally uncoupled from, that is independent from, the concentration of other components of the sample on the cell 31. [emphasis added]" See page 16:20-30. For claim 4 further note that admittance is the reciprocal of impedance. See the Bedell article, especially the second full paragraph on page 328 and the last full paragraph on

page 332. Thus, barring a contrary showing, having the response comprise an admittance value is an obvious variant of a response that has an impedance value.

1. Claims 60-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al. (US 6,743,635 B2) ("Neel").

Addressing claim 60, Neel discloses a test strip for performing a measurement on a biological fluid comprising:

a capillary fill chamber (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

at least two measurement electrodes (22,24) inoperative communication with the chamber (Figures 2 and 3), and

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber (Figure 2);

wherein the dose sufficiency electrodes have first edges substantially parallel to the length of the capillary chamber and second edges substantially perpendicular to the length of the capillary fill chamber (Figure 2).

Neel does not specifically mention having the first edges be of a greater length than the second edges and, in fact, Figure 2 shows that second edges being of a greater length than the first edges. However, Neel does teach that the capillary chamber may have different widths in different sections and more particularly that the

capillary fill chamber portion over the dose sufficiency electrodes may be made narrower than shown. See col. 08:04-17. This would, of course, go towards making the length of the first edges greater than the length of the second edges. Barring a contrary showing, such as unexpected results, having the length of the first edges be greater than the length of the second edges is just a consequence of optimizing the widths of different portions of the capillary fill chamber so that the sample adequately and quickly fills the capillary fill chamber.

Addressing claim 61, Neel discloses a test strip for performing a measurement on a biological fluid comprising:

a capillary fill chamber (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

a measurement zone in the chamber positioned intermediate the opening and the terminus (volume of the chamber above the measurement electrodes (22,24),

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber the electrodes positioned intermediate the measurement zone and the terminus (Figures 2 and 3);

wherein the dose sufficiency electrodes have a first axis substantially parallel to the length of the capillary chamber and a second axis substantially perpendicular to the length of the capillary fill chamber (Figure 2).

Neel does not specifically mention having the first axis be of a greater length than the second axis and, in fact, Figure 2 shows that the second axis has a greater length than the first axis. However, Neel does teach that the capillary chamber may have different widths in different sections and more particularly that the capillary fill chamber portion over the dose sufficiency electrodes may be made narrower than shown. See col. 08:04-17. This would, of course, go towards making the length of the first axis greater than the length of the second axis. Barring a contrary showing, such as unexpected results, having the length of the first axis be greater than the length of the second axis is just a consequence of optimizing the widths of different portions of the capillary fill chamber so that the sample adequately and quickly fills the capillary fill chamber.

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Addressing claim 62, Neel discloses a test strip for performing a measurement on a biological fluid comprising:

a fluid flow path (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

at least two measurement electrodes (22,24) inoperative communication with the chamber (Figures 2 and 3), and

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber (Figure 2);

wherein the dose sufficiency electrodes have first edges substantially parallel to the length of the capillary chamber and second edges substantially perpendicular to the length of the capillary fill chamber (Figure 2).

Neel does not specifically mention having the first edges be of a greater length than the second edges and, in fact, Figure 2 shows that second edges being of a greater length than the first edges. However, Neel does teach that the capillary chamber may have different widths in different sections and more particularly that the capillary fill chamber portion over the dose sufficiency electrodes may be made narrower than shown. See col. 08:04-17. This would, of course, go towards making the length of the first edges greater than the length of the second edges. Barring a contrary showing, such as unexpected results, having the length of the first edges be greater than the length of the second edges is just a consequence of optimizing the

widths of different portions of the capillary fill chamber so that the sample adequately and quickly fills the capillary fill chamber.

Addressing claims 63 and 65, for the additional limitations of these claims see col. 06:60 – col. 07:12 in Neel.

Addressing claim 64, Neel discloses a test strip for performing a measurement on a biological fluid comprising:

a fluid flow path (88) extending a length along the test strip from an intake opening (68) to a terminus (70),

a measurement zone in the chamber positioned intermediate the opening and the terminus (volume of the chamber above the measurement electrodes (22,24),

at least two dose sufficiency electrodes (60, 62) in operative communication with the chamber the electrodes positioned intermediate the measurement zone and the terminus (Figures 2 and 3);

wherein the dose sufficiency electrodes have a first axis substantially parallel to the length of the capillary chamber and a second axis substantially perpendicular to the length of the capillary fill chamber (Figure 2).

Neel does not specifically mention having the first axis be of a greater length than the second axis and, in fact, Figure 2 shows that the second axis has a greater length than the first axis. However, Neel does teach that the capillary chamber may have different widths in different sections and more particularly that the capillary fill chamber portion over the dose sufficiency electrodes may be made narrower than shown. See col. 08:04-17. This would, of course, go towards making the length of the first axis greater than the length of the second axis. Barring a contrary showing, such as unexpected results, having the length of the first axis be greater than the length of the second axis is just a consequence of optimizing the widths of different portions of the capillary fill chamber so that the sample adequately and quickly fills the capillary fill chamber.

It should be noted that the limitation of having the dose sufficiency electrodes be located between the measurement zone and the terminus is met by Neel even though they extend beyond the terminus because (a) the effective areas of the dose sufficiency electrodes, that is the exposed protons of the dose sufficiency electrodes, are before the terminus, but after the measurement zone; (b) the configurations of the dose sufficiency electrodes of Neel in which the portions beyond the terminus of the fill chamber are covered by dielectric material is similar to or the same arrangement as Applicant's embodiments shown in Figures 35A, 35B, and 36,which read on the claims; and (c) in any event, Neel discloses that the does sufficiency electrodes *may* be covered by dielectric material, which suggests that they alternatively may not be (col. 06:11-33), that is regions 60 and 62 may be increased.

Allowable Subject Matter

14. Claims 41-59 allowed are allowed for the reasons set forth in the Office action of September 25, 2007

Final Rejection

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1795
March 29, 2008